REMARKS

This paper is responsive to the Office Action mailed November 24, 2010. In the Office Action, the Examiner issued a final rejection of claims 1, 2, 4, 6-8, 10, and 21-33. For the following reasons, reconsideration of the rejections is respectfully requested.

35 USC 103(a) rejections:

Claims 1, 2, 4, 6-8, 10, 21-30 and 33 were finally rejected under 35 USC 103(a) as being unpatentable over Hoste (US 6,508,806)("Hoste") in view of van Muiden (EP 0662385)("van Muiden").

As stated in the present application, introducer sheaths are typically used as a conduit through which a medical interventional device, such as a stent, can be introduced into the vasculature. Introducer sheaths are typically thin-walled tubular devices that are fitted to an inner dilator for percutaneous placement over a wire guide. Such sheaths are commonly formed as composite constructions consisting of an inner liner formed of a low friction, lubricous material such as PTFE, an intermediate reinforcing layer consisting of a braid or a coil, and an outer layer formed of a thermoplastic compound such as a polyamide, polyethylene, or polyurethane.

Prior art introducer sheaths that incorporate a braid as the intermediate reinforcing layer generally do so to enhance the torqueability of the device. Braids are known to enhance torque control, which enhanced control assists the physician when directing a preformed tip into branch arteries and vessels. This action allows the accurate placement of stents and balloon angioplasty catheters in precise, distal locations. Prior art introducer sheaths that utilize a coil as an intermediate layer generally do so to enhance the kink resistance of the device. This allows the physician to manipulate the guide catheter or sheath external to the patient without kinking, and to conform to tortuous anatomy within the patient. If an introducer sheath kinks, the lumen size and

the ability of the sheath to freely deliver other devices, such as stents, will normally be compromised. (paragraph [0003], version as filed).

It is desirable to maintain the wall thickness of an introducer sheath as thin as possible. In this manner, the largest possible interventional device can be passed into a body vessel through a sheath that has been inserted through the smallest possible entry hole. Thus, most sheaths are provided with no more than a single reinforcement, in order to avoid the increased wall thickness necessitated by stacking two reinforcements in the same sheath. In addition, the presence of two reinforcements may result in one reinforcement interfering with the other. In this case the resulting device may have neither good torqueability nor good kink resistance. Interference of this type would be even more problematic when the reinforcements are positioned in close proximity to each other in the sheath. (paragraph [0005]).

Claims 1, 2, 4, 6-8, 10 and 33:

Claim 1 of the present application addresses the problem of providing a sheath having both torqueability and kink resistance, while at the same time minimizing the wall thickness of the sheath. The method of manufacturing the sheath as described in claim 1 is neither taught nor suggested by the art of record.

According to this method, a coil is positioned over a mandrel, and a first polymeric sleeve is positioned over the coil and the mandrel. The first polymeric sleeve comprises a first striped extrusion arranged in a generally helical pattern along an outer surface of the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch extending in a generally opposite direction from a pitch of the first striped extrusion. The assembly is positioned in a heat shrink tube, and heated to a temperature sufficient to cause the heat shrink material to shrink, whereby the first and

second polymeric sleeves melt together to form a tubular polymeric sheath. The second striped extrusion is superposed over the first striped extrusion in the sheath body.

As the first and second polymeric sleeves melt together, the striped extrusions having the opposing pitches are drawn together in the heat shrink tube to define a generally braid-like configuration. At the same time, the melted polymeric sleeves envelope the coil. As a result, a relatively thin-walled sheath is formed that provides both kink resistance (from the coil) and torqueability (from the braid-like configuration).

Hoste teaches a method of making an introducer sheath wherein a coil is positioned over a braid (or vice versa) to form a dual layer reinforced wall, which reinforced wall construction is stabilized in a polymeric matrix. However, Hoste does not teach positioning two sleeves with striped extrusions on a coil, and heating the resulting assembly, as claimed herein. Van Muiden was cited for teaching a method wherein a second sleeve with a striped helical pattern was positioned over a first sleeve to define a braid-like configuration.

Hoste teaches a catheter construction for use, e.g., in guiding or angiography catheters for angioplasty procedures. Hoste specifically points out that it is an important feature of such catheters to have as thin a catheter wall as possible. Nonetheless, when designing his catheter, Hoste utilized a stacking arrangement wherein the first reinforcing member is stacked on the second reinforcing member. Clearly, such construction increases the wall thickness, or radial extension, of the catheter when compared to a catheter having a single reinforcing member, since it is necessary to provide sufficient space along the catheter wall for each of the two reinforcing members. Thus, although Hoste recognized the problem of excessive wall thickness, and the desirability of providing as thin a catheter wall as possible, his solution does not alleviate this problem of wall thickness. In fact, his design adds additional structure (e.g., the second reinforcing member), and therefore additional

thickness, to the wall when compared to an otherwise similar sheath having a single reinforcing member.

As stated by the Examiner, van Muiden teaches that it is known to form reinforcing members by positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a substitute for a braid. An extrusion profile 30 is made up of two coaxial layers 31, 32, each having a number of extruded helically shaped bands of material. The bands of material 33 in the outermost layer 31 are running in the opposite direction to the helically shaped bands of material 34 in the innermost layer 32. Upon extrusion, a bond can be formed between the two layers with the helically shaped layers of material formed inside.

However, as shown in Fig. 4 of van Muiden, the sheath maintains the integrity of the separate layers 31, 32. Thus, even though van Muiden recognizes the trend toward ever thinner catheters (Col. 1, line 17), he maintains two separate layers in order to provide his substitute for a conventional braided reinforcement. In fact, according to van Muiden, the combination of the two layers is necessary to provide the effect of only a single reinforcing element, in this case a braid. No teaching or suggestion of a heat shrink step to radially compress the layers is provided. Thus, even though van Muiden recognized the desirability of providing a thin-walled catheter, he designed an arrangement wherein the integrity of two extruded "stacked" layers is maintained.

In addition to the foregoing, van Muiden provides no teaching or suggestion of a manner by which his structure can be combined with a coiled reinforcement. Nor is it apparent how this could be done without adding still more thickness to the wall of the catheter. Hoste provides no teaching or suggestion of achieving a braid function by melting two layers together in his heat shrink.

Thus, it is clear that the cited references, either individually or in combination, fail to teach or suggest a sheath capable of both enhanced torqueability and kink resistance, and at the same time, maintaining a thin sheath wall.

Unlike either of the cited references, the method of claim 1 addresses the problem of providing both kink resistance and torqueability in a thin-walled sheath by positioning dual polymeric sleeves over a mandrel in the manner described above. A separate coil reinforcement is provided, and the sleeves are melted together in a manner such that the sheath outer layer includes the superposed striped extrusions that define the braided reinforcement. Thus, separate defined sleeves for providing these features are not required. Similarly, a discrete outer layer is also not required. Neither reference teaches or suggests such an elegant arrangement as claimed herein.

Although the Examiner contends that the claim can be derived by combining the subject matter of Hoste and van Muiden, the applicant respectfully disagrees. The shrink jacket process of Hoste necessitates the presence of two reinforcing members radially arranged along the wall thickness. Even as the heat shrink is carried out, the presence of the reinforcing members occupy space in the wall. The Examiner acknowledges this deficiency in Hoste with his statement that "The examiner interprets that the shrink jacket process of Hoste when modified by van Muiden would form an assembly where the sleeves are melted together to obtain a braid configuration." OA, page 3.

Applicant respectfully states that this rationale is untenable for multiple reasons. It is clear that van Muiden does not teach or suggest that a reduction in wall thickness results from his dial extrusion layers. This is clearly evident in his Fig. 4. Thus, the step of forming a sheath having the generally braid-like configuration by melting together two sleeves in a heat shrink tube is *not* taught or suggested in van Muiden. Thus, even when Hoste's process is modified by incorporating the teachings of van Muiden,

those teachings do not support melting the layers of van Muiden together to form a braid-like configuration. Clearly, neither reference gives any indication that this heat shrink step can, or even should, be carried out to achieve a braid function. Further, in the absence of a teaching or suggestion in either reference to form a braid-like configuration *by melting together two sleeves having opposing striped extrusions to form a single layer* as described, it is difficult to understand how this teaching can be derived from their combination without the exercise of inventive contribution.

Applicant respectfully submits that the test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference, but rather, what the combined teachings of the references would have suggested to those of ordinary skill in the art. Further, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In making a prima facie determination of obviousness, the Examiner should identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Applicant respectfully submits that a prima facie case of obviousness of claim 1 in view of the cited combination has not been set forth by the Examiner. Each of the references recognizes the desirability of providing a thin-walled sheath, yet the references fail to teach or suggest the solution to the problem arrived at by the present claims. In fact, Hoste maintains a structure having discrete layers 17, 18, 19 as described. Van Muiden's combination of the dual outer sleeves does not advance the desire of maintaining a low wall thickness in the elegant manner as claimed herein. Applicant submits that no articulated reasoning with rational underpinning has been provided to support the obviousness finding, as required, and that it is

only after the benefit of Applicant's disclosure is gained that the features of the invention may appear to be obvious.

In the present rejections, each of the cited references recognizes the desirability of providing a thin-walled catheter. Notwithstanding this desirability, neither reference was able to arrive at a solution to this problem in the manner of the claimed method. Applicant submits that absent the application of hindsight utilizing the present claims as a blueprint, the solution is not derivable from the cited combination.

For at least the foregoing reasons, reconsideration of the obvious rejections of claim 1, and the claims depending therefrom, is respectfully requested.

Claims 21-30:

Claim 21 is also directed to a method of manufacturing an introducer sheath. The steps as recited in this claim are generally illustrated in the figures, such as the sequence of Fig. 6. As stated above, the cited art does not teach or suggest the feature of combining first and second sleeves having respective striped extrusions as described over an inner liner and a coil, and melting the first and second sleeves in a heat shrink enclosure to form an outer tube (e.g., paragraphs [0029] and [0032]). In this manner, a sheath is obtained having the desirable features of 1) a thin wall; 2) enhanced kink resistance provided by the radially inner coil; and 3) enhanced torqueability provided by the braid-like arrangement of the first and second striped extrusions. Such a sheath is clearly not derivable from the prior art methods referenced by the Examiner, either individually or in combination.

The Examiner has acknowledged that Hoste does not explicitly teach the "positioning" steps of the claimed method that involve the arrangement of the two polymeric sleeves. Accordingly, Hoste also cannot teach or suggest the "heating" step that causes the first and second "positioned" sleeves to melt together to form the *outer* tubular layer. Van Muiden was said to teach a

two layer polymer sleeve for a catheter including striped helical patterns for defining a braid-like configuration. Van Muiden, however, does not teach or suggest the manner of achieving the braid-like action in a thin-walled sheath by melting the two extruded layers together. Applicant respectfully submits that the combined disclosures of the cited references fall well short of teaching or suggesting the claimed method. There is no basis, other than hindsight, for combining these two references in a manner to construct a dual reinforcement sheath, since no such teaching or suggestion is provided in either reference. Further, even when such impermissible hindsight is utilized, the combination falls short of the features of the claimed method.

Claims 22-30 depend from claim 21, directly or indirectly, and therefore include all of its limitations. Accordingly, these claims are also not obvious in view of the cited combination for at least the same reasons that claim 21 is not obvious.

Claims 31-32:

Claims 31 and 32 were rejected under 35 USC 103(a) as being unpatentable over Hoste in view of van Muiden, as applied to claims 21 and 27, and further in view of Garabedian et al. (US 6,171,295)("Garabedian").

Each of claims 31 and 32 depends, indirectly, from claim 21, and therefore, includes all of its limitations. Garabedian does not teach or suggest the features described above that are lacking when the Hoste/van Muiden combination is made. Accordingly, claims 31 and 32 are also not obvious for at least the same reasons that claim 21 is not obvious.

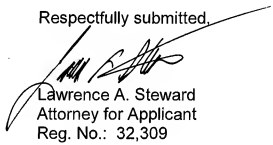
Conclusion:

Based upon the foregoing, Applicant respectfully requests reconsideration of the rejections of claims 1-2, 4, 6-8, 10, and 21-33. Although each of the cited references acknowledges the desire for providing a thin-walled sheath, as the Examiner stated in the Office Action, the

references, when considered individually or in combination, do not teach or suggest a means for achieving this desired structure. Upon reviewing the cited references, one skilled in the art would still not be able to combine the coil and braid functions in a thin-walled sheath as claimed. Hoste doesn't provide such a teaching, nor does van Muiden with his dual sleeve braid functionality. The skilled artisan would have no basis to achieve the solution claimed herein from a review of these teaching. Accordingly, reconsideration is requested.

If the Examiner believes that further prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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